REMARKS

The amendments above and the remarks below are in response to a Final Office Action mailed on August 19, 2008. In the Office Action, Claims 1-5, 9-12, 15-16 and 19-20 were rejected under 35 U.S.C. 103(a) over U.S. Pats. Nos. 5,156,596 to Balbierz et al. ("Balbierz") and 5,092,846 to Nishijima et al. ("Nishijima"). Claims 1-5, 9-12, 15-16 and 19-20 were rejected under obviousness-type double patenting over U.S. Pats. Nos. 6,827,710 and 6,592,544.

Reexamination and reconsideration of the application are respectfully requested. A Request for Continued Examination (RCE) is hereby made. A one-month extension of time to respond is also hereby requested, and the fee is being paid concurrently herewith.

With respect to the double-patenting rejection, without conceding the appropriateness of the rejection and for expedient prosecution, a terminal disclaimer is enclosed disclaiming any term over the commonly assigned U.S. Pats. Nos. 6,827,710 and 6,592,544. The double-patenting rejection has therefore been overcome. In addition, a newly signed Power of Attorney by the assignee has been submitted allowing the undersigned attorney's signature of the Terminal Disclaimer.

Independent Claims 1 and 15 have been amended to recite a side arm opening immediately downstream with respect to the hemostasis valve.

Balbierz

An insertion assembly 11 shown in Figure 1 of Balbierz includes a needle hub 12 supporting a needle 18. The needle hub fits within an outer cannula hub 22 and the needle extends through an outer cannula 28 supported by the cannula hub. The needle and outer cannula are inserted into a vein and the needle withdrawn, leaving only the outer cannula. Col. 7; ll. 14-21 of Balbierz. The outer cannula hub includes a valve means 70, as shown in Figures 3 and 4 of Balbierz. The valve means 70 includes a self sealing septum 72.

Balbierz also discloses a multi-lumen catheter assembly 10, as shown in Figure 5. The multi-lumen catheter assembly 10 includes a positioning assembly 38 with Luer locking mechanism 66 that attaches it to the insertion assembly, as shown in Figures 3 and 4 of Balbierz. The catheter includes an inner cannula 52 with a distal end portion 56 "that extends beyond the

distal end portion 32 of the outer cannula 28." Col. 7; ll. 45-47 of Balbierz. The other end of the inner cannula is fed by a proximal access region 48, as shown in Figure 4 of Balbierz.

Notably, inner cannula 52 extends from the side arm of the Y-shape through and out of the outer cannula without fluid communication between the lumen of the inner cannula and the outer cannula.

In contrast, the presently claimed invention recites a side arm opening immediately downstream with respect to the hemostasis valve. For at least that reason, Balbierz alone does not teach or suggest the present invention as recited in the claims. In fact, it was admitted in the final Office Action that Balbierz does not teach a side arm opening distal of a hemostasis valve.

Nishijima

Nishijima discloses a catheter introducer that includes a body 2 defining an inner cavity 11 that is distal to a valve means 3, as shown in Figure 1B. A sheath tube 5 is connected to the body so that it communicates with the inner cavity. The body also includes a branching member 7 which is connected to a connecting tube 8 for the injection of heparin or saline into the inner cavity. A dilator 12 that is connected to a grip 13 can be inserted through the valve means for dilating openings. A catheter 4 can be inserted through the dilator, as shown in Figure 1A of Nishijima.

Nishijima, among other aspects, does not teach or suggest the multi-function adapter with compelementary units that converts the infusion introducer into a multiple lumen access device with main and auxiliary channels. Therefore, Nishijima alone also does not teach or suggest the presently claimed invention.

Alleged Combination of Balbierz and Nishijima

One of ordinary skill in the art would not combine Balbierz and Nishijima. Balbierz, when differentiating the prior art, teaches against introduction of liquids immediately downstream of a septum (which is analogous to a valve) because of undesirable stagnation.

> Also, any liquids being flowed through the outer cannula lumen (i.e., through the annular space between the inner and outer cannulae) must be introduced downstream of the septum whereby the space immediately downstream of the septum (and upstream of the introduction of the liquid) is substantially stagnant.

> Furthermore, the fact that this space is not flushed out means that if the fluid being flowed through the outer cannula lumen is changed, there will be a transition time during which a mixture of the old and new fluids will be present. As some medicaments are not compatible with others such mixing can be undesirable.

See, col. 2, ll. 1-12 of Balbierz. Nishijima teaches this same structure that Balbierz deplores, its branching member connects to inner cavity 11 which is downstream to the valve means 3, as shown in Figure 1B.

As noted above, there is no fluid communication between the lumen of the inner and outer cannulae. Balbierz stresses the importance of this design several times. "The distal end portion 56 of the inner cannula 52, in the embodiment illustrated, extends beyond the distal end portion 32 of the outer cannula 28. In this manner non-compatible medicaments can be introduced into a blood vessel or other body cavity a spaced distance apart from one another. Or, samples can be removed from a region of the vessel or cavity which is free of a particular medicament which is being introduced via another lumen." Col. 7; ll. 45-53 of Balbierz.

Balbierz also stresses the importance of not introducing flow downstream of the valve. "It is also important to understand that flow from the second passage 42 into the outer cannula lumen 34 washes through and cleanses the valve means 70 thereby eliminating any dead space which would be present if the flow into the outer cannula lumen 34 was introduced downstream of the valve means 70." Nishijima teaches the end of the branching member opening into the cavity 11 of the main body 2 which communicates with sheath tube 5. Thus, one of ordinary skill in the art would view Nishijima as disclosing an assembly that causes mixing of non-compatible medicaments and stagnation of flow in the "dead space" immediately downstream of the valve.

Even if one were (erroneously) inclined to combine Balbierz with Nishijima, such a combination would not result in the presently claimed invention. As described above, the inner cannula 52 of Balbierz extends from the side arm of the Y-shape through, and out of, the outer cannula without fluid communication between the lumen of the inner cannula and the outer cannula. Inserting the cannula of Balbierz through the introducer of Nishijima would result in the side arm extending out of the introducer of Nishijima, with no fluids introduced through the side arm ending up immediately downstream of the valve, as recited in the presently claimed invention.

Thus, the present invention as recited in Claims 1 and 15 represents a surprising result over the teachings of the prior art. In particular, Claims 1 and 15 recite an access device with an adapter that converts an introducer into a multiple lumen access device with at least two channels and a side arm opening positioned immediately downstream of a hemostasis valve. The remaining Claims 4-5, 9-12 and 16-20 depend from, and further patentably distinguish, Claims 1 and 15. The rejection under 35 U.S.C. 103(a) has therefore been overcome.

CONCLUSION

In view of the remarks and amendments presented above, it is respectfully submitted that the pending claims of the present invention are in condition for allowance. It is respectfully requested that a Notice of Allowance be issued in due course. The Examiner is requested to contact Applicants' undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

The Commissioner is hereby authorized to charge the required fees for the Request for Continued Examination (RCE) and **One-Month** extension of time to Deposit Account No. 50-1225. If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge said fees, such as under 37 C.F.R. §§ 1.16 or 1.17, or to credit any overpayment, to Deposit Account No. 50-1225 referencing Attorney Docket No. ECC-5062CIP2DV.

Respectfully submitted,

Date: December 19, 2008

Gregory J. Carlin, Reg. No. 45,607
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6856
Facsimile: (949) 250-6850
Customer No. 30452